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MAY 17 2011

Section 6: 510(k) Summary

Trade Name:	ChitoGauze™ FUSION™ Wound Packing Kit
Common Name:	Wound Dressing
Classification Name:	Dressing
Product Code:	FRO
Predicate Device(s):	Modification to ChitoGauze™XR (K090026, K092357, K102546)
Company Name:	HemCon Medical Technologies, Inc.
Company Address:	10575 SW Cascade Avenue, Suite 130 Portland, OR 97223
Contact Person:	Kendra Rathkey Regulatory Affairs Lead
Contact Phone:	(503) 245.0459 x139
Contact Fax:	(971) 327.5725
Date of Preparation:	21 April 2011

Description of the Device:

ChitoGauzeXR is composed of polyester/rayon blend non-woven medical gauze coated with chitosan and with a radiopaque filament attached. The legally marketed ChitoGauzeXR dressing has been modified to co-package the ChitoGauzeXR hemostatic dressing with uncoated polyester/rayon blend non-woven medical gauze (also referred to as "uncoated gauze") to create the ChitoGauze FUSION Wound Packing Kit.

ChitoGauze FUSION may be produced in multiple sizes within the scope of the currently validated sizes of the ChitoGauze family of dressings. Both the ChitoGauzeXR and the uncoated gauze are Z-folded to the appropriate size and contain a radiopaque element. To visually distinguish between the two, the ChitoGauzeXR dressing contains one radiopaque yarn and the uncoated gauze contains two radiopaque yarns. The dressings are co-packaged in a pouching configuration consisting of an inner dispenser pouch and outer pouch. The inner nylon/LDPE pouch will hold both gauze components and is intended to allow controlled dispensing of the gauze dressings through a hole on top. Because there is a hole on tope, this pouch is not intended to act as a sterile barrier. The outer foil pouch is intended to provide a barrier to protect the product and maintain product sterility.

The ChitoGauze FUSION Wound Packing Kit is terminally sterilized with gamma irradiation to a sterility assurance level (SAL) of 10^{-6}.

The hemostatic properties of chitosan enhance the ability of the ChitoGauzeXR to control bleeding. The uncoated gauze is intended to be used as a backing or securement dressing and to absorb excess fluid. The co-packaging of the two gauze

types provides an added level of convenience to the user and facilitates ease-of-use. The radiopaque filament allows for easy detection via x-ray to prevent the dressing from being inadvertently left on the wound.

Intended Use:

The ChitoGauze FUSION Wound Packing Kit is intended to be a hemostatic wound dressing.

Indications for Use (Rx):
The ChitoGauze FUSION Wound Packing Kit is a hemostatic dressing for the external, temporary control of severely bleeding wounds.

Technological Characteristics:

The ChitoGauze FUSION Wound Packing Kit is technologically equivalent to the currently marketed ChitoGauzeXR dressing. Co-packaging ChitoGauzeXR with uncoated gauze in an inner dispensing pouch does not affect the fundamental scientific technological characteristics of the original ChitoGauzeXR.

Non-Clinical Performance Data:

Biocompatibility
Biocompatibility testing was performed on ChitoGauze FUSION per ISO 10993. This testing confirmed that co-packaging ChitoGauzeXR with uncoated gauze in an inner dispensing pouch has no effect upon the biocompatibility of the device.

In Vivo Efficacy
Two separate in vivo studies were designed and conducted to establish the hemostatic efficacy of the ChitoGauze product in different injury types created to represent the simulated use of the different product sizes. In both studies the device was tested side-by-side against a competitive hemostatic dressing. The first study tested the ability of the 4 inch by 4 yard size to control bleeding in 6mm femoral perforation injury in a swine. The second study measured the ability of a two inch by two inch 8-ply size to control bleeding in a splenic capsular strip injury in a swine. In both cases, the device proved to successfully control bleeding at least as well as the competitive product used as a reference.

Reduction of Microorganisms:
The ChitoGauze FUSION chitosan-coated gauze dressing was tested for reduction of microorganisms against the following species. The log reduction data demonstrates the level of antibacterial effectiveness; see table 2 below. The clinical utility of these results is unknown.

Table 2: Log reduction of microorganisms demonstrating level of antibacterial effectiveness of ChitoGauze™ FUSION™ hemostatic gauze.

Organism	Gram Stain	Log Reduction
Escherichia coli ATCC 8739	-	>5.4
Klebsiella pneumoniae ATCC 4352	-	>5.0
Streptococcus pyogenes ATCC 19615	+	>5.1
Staphylococcus aureus ATCC 33591	+	5.4
Staphylococcus epidermidis ATCC 12228	+	>5.4
Salmonella choleraesuis ATCC 10708	-	>5.2
Pseudomonas aeruginosa ATCC 9027	-	>5.2
Enterococcus faecalis ATCC 51299	+	4.8
Enterococcus faecalis ATCC 700802	+	>5.1
Serratia marcescens ATCC 13880	-	>5.1
Stenotrophomonas maltophilia ATCC 12714	-	>5.5
Streptococcus mutans ATCC 25175	+	>5.0
Clostridium difficile ATCC 9689	+	>5.3
Streptococcus pneumoniae ATCC 10015	+	>5.1
Citrobacter koseri ATCC 25408	-	>5.4
Shigella species ATCC 11126	-	>5.3
Enterobacter aerogenes ATCC 13048	-	>5.4
Proteus mirabilis ATCC 4630	-	>4.9
Proteus vulgaris ATCC 12454	-	>5.2
Citrobacter freundii ATCC 8090	-	>5.5
Enterobacter cloacae ATCC 13047	-	>5.1
Acinetobacter baumanii ATCC 15308	-	>4.3
Moraxella catarrhalis ATCC 8193	-	>5.3
Micrococcus luteus ATCC 49732	+	>5.5
Vibrio cholerae ATCC 11558	-	5.5
Staphylococcus aureus ATCC BAA-1556	+	4.6

Sterility

A sterility validation for the ChitoGauze FUSION Wound Packing Kit was completed following ISO 11137:2006 requirements to demonstrate a 10^{-6} SAL using the VD_{max}^{25} method.

Radiopacity:

The radiopacity of ChitoGauzeXR was determined via testing performed in accordance with ASTM F640-07 Method C (Standard Test methods for Determining the Radiopacity for Medical Use). The product was found to be equivalent to the radiopacity of the ASTM Radiopacity Standard (101x76x0.9 mm 99+% 1100 alloy aluminum sheet) and was therefore determined to be acceptable.

Clinical Performance Data:

No clinical data was required for evaluation of this device.

Conclusion:

The modification to co-package ChitoGauzeXR with uncoated gauze in an inner dispensing pouch is neither a change to the intended use, nor an alteration of the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

HemCon Medical Technologies, Inc.
% Ms. Kendra Rathkey
Regulatory Affairs Lead
10575 SW Cascade Avenue, Suite 130
Portland, Oregon 97223-4363

MAY 17 2011

Re: K111163
Trade/Device Name: ChitoGauze™ FUSION™ Wound Packing Kit
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 22, 2011
Received: April 26, 2011

Dear Ms. Rathkey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 5: Indications for Use Statement

Applicant: HemCon Medical Technologies, Inc.
510(k) Number:
Device Name: ChitoGauze™ FUSION™ Wound Packing Kit

Indications for Use (Rx):

The ChitoGauze™ FUSION™ Wound Packing Kit is a hemostatic dressing for the external, temporary control of severely bleeding wounds.

Prescription Use ☒ (Part 21 CFR 801 Subpart D) AND/OR **Over-The-Counter Use** ☐ (21 CFR 801 Subpart C)

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111163